

PATENT  
Attorney Docket No. 402091/SKYE PHARMA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MISHRA et al.

Group Art Unit: 1617

Application No. 09/820,371

Examiner: E. Webman

Filed: March 26, 2001

For: INJECTABLE AQUEOUS DISPERSIONS  
OF PROPOFOL

*IDS and PTO  
1449 Forms as  
submitted on  
Jan. 24, 2004 in  
USSN 09/820,371*

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☐ within any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☒ **after (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:**
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☒ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).**
- ☐ **after the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and *within* thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).**

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

- ☐ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☒ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1. 09/376,487	August 18, 1999		X	
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The undersigned hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The undersigned hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The undersigned hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☐ No fee is owed by the applicant(s).
- ☒ The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$
- ☒ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of Mishra et al.  
Application No. 09/820,371

**Instructions as to Overpayment**

☒  
☐

Credit Account No. 12-1216.  
Refund

Respectfully submitted,



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Date:  
LOR:ves

1/24/03

**INFORMATION DISCLOSURE  
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

121-175

09/376,487

APPLICANT

MISHRA et al

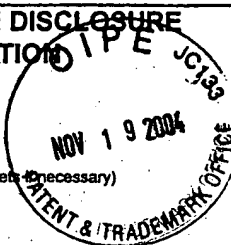
FILING DATE

GROUP

August 18, 1999

1617

(Use several sheets if necessary)



**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,589,508	12/96	Schlotzer et al			

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
0 770 387 A1	5/97	Europe			

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)**


\*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)



**SERIAL NO.**

09/376,487

APPLICANT

MISHRA et al

FILING DATE

**GROUP**

August 18, 1999

1617

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**OTHER DOCUMENTS** (including Author, Title, Date, Pertinent pages, etc.)


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Form PTO-FB-A820 (Also PTO-1449)





Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

2

**Complete if Known**

Application Number	9/376,487
Filing Date	August 18, 1999
First Named Inventor	MISHRA
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090

**U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
	1	4,056,635		Glen et al.	11/1/1977	
	2	4,280,996		Okamoto et al.	7/28/1981	
	3	4,309,421		Ghyczy et al.	1/5/1982	
	4	4,340,594		Mizushima et al.	7/20/1982	
	5	4,687,762		Fukushima et al.	8/18/1987	
	6	4,837,028		Allen	6/6/1989	
	7	4,880,634		Speiser	11/14/1989	
	8	4,895,726		Curtet et al.	1/23/1990	
	9	5,023,087		Yau-Young	6/11/1991	
	10	5,100,591		Leclef et al.	3/31/1992	
	11	5,320,906		Eley et al.	6/14/1994	
	12	5,527,537		Dietl	6/18/1996	
	13	5,827,520		de Salvert	10/27/1998	
	14	5,827,536		Laruelle	10/27/1998	
	15	5,880,148		Edgar et al.	3/9/1999	
	16					

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	17	DE	25 13 797		ICI Ltd.	10/9/975		X+
	18	DE	29 38 807		Green Cross Corp.	11/13/1980		X+
	19	DE	3421 468		Rentschler Arzenimittel	12/19/1985		X+
	20	EP	052 322		Gersonde Klaus Prof Dr	5/26/1982		X+
	21	EP	057 829		Fullard	8/18/1982		
	22	EP	272 091		Vestar, Inc.	6/22/1988		
	23	EP	330 532		Fournier Innovation Synergie	8/30/1989		X+
	24	EP	391 369		Yissum Research Dev.	10/10/1990		
	25	EP	418 153		Medgenix Group SA	3/20/1991		X+
	26	EP	456 670		Braun Melsungen AG	11/21/1991		X+
	27	EP	456 764		Braun Melsungen	11/21/1991		X+
	28	EP	499 299		Sterling Winthrop Inc.	8/19/1992		
	29	EP	535 567		Braun Melsungen AG	4/7/1993		X+
	30	EP	570 829		Hans	11/24/1993		X+
	31	EP	601 618		Sterling Winthrop Inc.	6/15/1994		
	32	EP	602 700		Sterling Winthrop Inc.	6/22/1994		
	33	EP	724 877		Fournier Lab SA	8/7/1996		X+
	34	EP	757 911		CLL Pharma	2/12/1997		X+
	35	EP	770 387		B. Braun Melsungen AG	5/2/1997		
	36	EP	770 381		Oreal	5/2/1997		X+

Examiner Signature

Date Considered

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	9/376,487
				Filing Date	August 18, 1999
				First Named Inventor	MISHRA
				Group Art Unit	1617
				Examiner Name	E. Webman
Sheet	2	of	2	Attorney Docket Number	402090

FOREIGN PATENT DOCUMENTS								
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	37	EP	814 787		AstraZeneca AB	1/7/1998		
	38	EP	1 238 677		AstraZeneca AB	9/11/2002		
	39	FR	2 265 357		ICI Ltd.	10/24/1975		X+
	40	FR	2 617 047		Sanofi SA/Fournier Labs.	12/30/1988		X+
	41	JP	55-141407		Nattermann A & CIE	11/5/1980		X+
	42	JP	56-167616		Green Cross Corp.	12/23/1981		X+
	43	JP	60-208910		Green Cross Corp.	10/21/85		X+
	44	JP	63-502117			8/18/1988		X+
	45	JP	63-233915		Besutaa Res. Inc.	9/29/1988		X+
	46	JP	1-502590		Liposome Tech. Inc.	9/7/1989		X+
	47	HU	211 580		Egis Gyogyszergy Rt.	12/28/1995		X+
	48	PCT	WO 85/00011		The University of Miami	1/3/1985		
	49	PCT	WO 87/04592		Liposome Tech. Inc.	8/13/1987		
	50	PCT	WO 91/04011		Riker Labs., Inc.	4/4/1991		
	51	PCT	WO 93/19736		Kabi Pharmacia AB	10/14/1993		
	52	PCT	WO 94/20072		Pharmacia AB	9/15/1994		
	53	PCT	WO 96/01637		Astra Aktiebolag	1/25/1996		
	54	PCT	WO 96/19064		Xcellenet, Inc.	6/20/1996		
	55	PCT	WO 96/21439		Galephar P.R. Inc.	7/18/1996		
	56	PCT	WO 96/29064		Zeneca Ltd.	9/26/1996		
	57	PCT	WO 97/10814		Vesifact AG	3/27/1997		
	58	PCT	WO 97/14407		Research Triangle Pharmaceuticals	4/24/1997		
	59	PCT	WO 98/53805		Saucy Ltd.	12/3/1998		
	60	PCT	WO 99/39696		Gensia Sicor Inc.	8/12/1999		
	61	PCT	WO 00/10531		RTP Pharma Inc.	3/2/2000		
	62	PCT	WO 00/24376		Abbott Labs.	5/4/2000		
	63	PCT	WO 00/54588		Krusz	9/21/00		
	64	PCT	WO 00/59471		Baxter International, Inc.	10/12/2000		
	65	PCT	WO 00/59472		Baxter International, Inc.	10/12/2000		
	66	PCT	WO 00/78301		Kuhnli Pharm. Co. Ltd.	12/28/2000		
	67	PCT	WO 01/30372		BASF Aktiengesellschaft	5/3/2001		X+
	68	PCT	WO 02/21517		Zeon Corp.	3/14/2002		X+
	69	UK	2 046 094		A. Nattermann & Cie	11/12/1980		
	70	UK	2 250 197		Egis Gyogyszergyar	6/3/1992		
	71	UK	2 298 789		Zeneca Ltd.	9/18/1996		

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary).				<b>Complete if Known</b>	
				Application Number	09/376,487
				Filing Date	August 18, 1999
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				Group Art Unit	1617
				Examiner Name	E. Webman
Sheet	1	of	3	Attorney Docket Number	402090/SKYE PHARMA

OTHER - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation		
			Yes	No**	
	1	"Diprivan 1% Injection," Physicians' Desk Reference, 1996, pp. 2833-39.			
	2	"Diprivan 1% Injection," Physicians' Desk Reference, 1999, pp. 3411-18.			
	3	Arduino, M.J. et al., "Microbial Growth and Endotoxin Production in the Intravenous Anesthetic Propofol", Infection Control and Hospital Epidemiology, Vol. 12, No. 9, September 1991, pp. 535-539.			
	4	Babl et al., "New Formulations of Propofol in an LCT/MCT Emulsion: Approach to Reduce Pain on Injection", Eur. Hosp. Pharmacy, January 1995, Vol. 1, No. 1, pp. 15-21.			
	5	Bangham et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids," J. Mol. Biol., 1965, 13:238-251.			
	6	Bennett et al., "Postoperative Infections Traced to Contamination of an Intravenous Anesthetic, Propofol", Vol. 333, No. 3, July 20, 1995, pp. 147-154.			
	7	Benz et al., "Electrical Capacity of Black Lipid Films and of Lipid Bilayers made from Monolayers," Biochimica et Biophysica Acta, 1975, 394:323-334.			
	8	Bergmann, Ludwig, Der Ultraschall, 5 Aufl., 1949, Stuttgart, pp. 551-564 and 665-677.			X
	9	Bittman, Robert, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," LIPIDS, Vol. 13, No. 10, pp. 686-691 (1978).			
	10	Cairns et al., "Tolerance of Mixed Lipid Emulsion in Neonates: Effect of Concentration", Archives of Disease in Childhood, 1996, Vol. 75, p. F113-F116.			
	11	Cherney, Leonid S., "Tetracaine Hydroiodide: A Long-Lasting Local Anesthetic Agent for the Relief of Postoperative Pain," Anesthesia and Analgesia, Vol. 42, No. 4, July-Aug. 1963, pp. 477-481.			
	12	Crowther et al., "Growth of Microorganisms in Propofol, Thiopental and a 1:1 Mixture of Propofol and Thiopental", Anesth. and Anal., (1996), 82, pp. 475-478.			
	13	Cudd et al., "Liposomes Injected Intravenously into Mice Associate with Liver Mitochondria," Biochimica et Biophysica Acta, (1984), 774:169-180.			
	14	De Sommer et al., "A Comparative Study on the Effects of Propofol in Emulsion and Intralipid® on Fat Metabolism," Acta Anesthesiologica Belgica, Vol. 41, No. 2, 1990, pp. 133-138.			
	15	Dewandre et al., "A Comparison of the 2% and 1% Formulations of Propofol During Anaesthesia for Craniotomy," Anesthesia, 1994, Vol. 49, pp. 8-12.			
	16	Doenicke, A.W. et al., "Pharmacokinetics and Pharmacodynamics of Propofol in a New Solvent", Anesth. Analg., (1997), 85:1399-403.			
	17	Doenicke, A.W. et al., "Reducing Pain During Propofol Injection: The Role of the Solvent", Anesth. Analg., (1996), 82:472-4.			

Examiner Signature		Date Considered	
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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**Complete if Known**

Application Number	09/376,487
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**OTHER - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	18	Eddleston et al., "The Effect on Serum Lipid Concentrations of a Prolonged Infusion of Propofol - Hypertriglyceridaemia Associated with Propofol Administration," Intensive Care Med., (1991), 17:424-426.		
	19	Ewart et al., "Forum: 2% Propofol for Sedation in the Intensive Care Unit, A Feasibility Study", Anaesthesia, February 1992, Vol. 47, No. 2, pp. 146-148.		
	20	Freeman, Andrew B., "A Technique for Reducing Pain Associated with Propofol Administration," Anesth. Analg., 1992, 74:311-319.		
	21	Ghouri et al., "Effect of Flumazenil on Recovery after Midazolam and Propofol Sedation", Anesthesiology, (1994), 81:333-339.		
	22	Goodman & Gillman's The Pharmacological Basis of Therapeutics, 7 <sup>th</sup> Ed., MacMillan Publishing Co., New York, 1985. p.312.		
	23	Gottardis et al., Effect of Prolonged Sedation with Propofol on Serum Triglyceride and Cholesterol Concentrations, British J. Anaesthesia, (1989) 62:393-396.		
	24	Gregoriadis, Gregory, "The Carrier Potential of Liposomes in Biology and Medicine", The New England Journal of Medicine, September 23, 1976, Vol. 295, pp. 704-710.		
	25	Haung et al., "Interaction of the N-terminus of Sterol Carrier Protein 2 with Membranes: Role of Membrane Curvature," Biochem. J., (1999), 344:593-603.		
	26	Haynes et al., "Ultra-Long Duration Local Anesthesia Produced by Intra-Dermal Injection of Lecithin-Coated Methoxyflurane Microdroplets", Proceed. Intern. Symp. Control. Rel. Bioact. Mater., (1987), 14:293-294 (Extended abstract)		
	27	Haynes et al., "Ultra-long-duration Local Anesthesia Produced by Injection of Lecithin-coated Methoxyfluorene Microdroplets", Anesthesiology, November 1985, Vol. 63, No. 5, pp. 490-499.		
	28	Haynes, Duncan H., "Divalent Cation-Ligand Interactions of Phospholipid Membranes: Equilibria and Kinetics," Metal-Ligand Interactions in Organic Chemistry and Biochemistry, Pullman and Goldblum, Eds., part 2, ©1977, pp. 189-212		
	29	King et al., "Lidocaine for the Prevention of Pain Due to Injection of Propofol," Anesth. Analg., 1992, 74:246-249.		
	30	Kirkpatrick et al., "Local Anesthetic Efficacy of Methoxyflurane Microdroplets in Man," Anesthesiology, 1987, 67(3A):A254, Abstract only.		
	31	Lindholm, Marianne, "Critically Ill Patients and Fat Emulsions," Minerva Anesthesiology, 1992, Vol. 58, No. 10, pp. 875-879.		
	32	Mangar et al., "Tourniquet at 50 mm Hg Followed by Intravenous Lidocaine Diminishes Hand Pain Associated with Propofol Injection", Anesth. Analg., (1992), 74:250-252.		
	33	Mirakhur et al., "Induction Characteristics of Propofol in Children: Comparison with Thiopentone", Anesthesia, (1998), 43:593-598.		
	34	Mishra et al., "Scientifically Speaking: Novel Injectable Formulations of Water-insoluble Drugs", Controlled Release Newsletter, Vol. 17, Issue 2, June 2000, pp.21-30		
	35	Nichols, Ronald Lee, "Bacterial Contamination of an Anesthetic Agent," New Engl. J. Med., (1995), 333(3), 184-185.		

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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Attorney Docket Number	402090/SKYE PHARMA

**OTHER - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	36	Rompp, "Emulsion", Chemie-Lexikon, 2 Aufl., Bd. 1, 1950, Stichwort.		
	37	Ross, et al., "Aqueous Solutions of Surface-Active Solutes", Colloidal Systems and Interfaces, © 1988, p. 148-151		X
	38	Sande et al., "Antimicrobial Agents: Antifungal and Antiviral Agents," p. 1219-1222.		
	39	Sandstrom et al., "Structured Triglycerides Were Well Tolerated and Induced Increased Whole Body Fat Oxidation Compared With Long-Chain Triglycerides in Postoperative Patients," Journal of Parenteral and Enteral Nutrition, (1995), 19(5):381-6.		
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STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/376,487
Filing Date	August 18, 1999
First Named Inventor	MISHRA
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

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Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

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\* References being submitted under separate cover



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			First Named Inventor	Awadhesh K. Mishra	
			Group Art Unit	1617	
			Examiner Name	E. Webman	
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Group Art Unit	1617
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

## **Complete if Known**

Application Number	09/376,487
Filing Date	8/18/99
First Named Inventor	Awadhesh K. Mishra
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

Sheet 7 of 12

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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12

**Complete if Known**

Application Number	09/376,487
Filing Date	8/18/99
First Named Inventor	Awadhesh K. Mishra
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

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		Application or Patent Number	Kind Code			
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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**Complete if Known**

Application Number	09/376,487
Filing Date	8/18/99
First Named Inventor	Awadhesh K. Mishra
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

Sheet 9 of 12

**U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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Application Number	09/376,487
Filing Date	8/18/99
First Named Inventor	Awadhesh K. Mishra
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

Sheet	10	of	12
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**U.S. PATENT DOCUMENTS**

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		Application or Patent Number	Kind Code			
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

Application Number	09/376,487
Filing Date	8/18/99
First Named Inventor	Awadhesh K. Mishra
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPhARMA

Sheet 11 of 12

**U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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Examiner Signature		Date Considered	
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Application Number	09/376,487
Filing Date	8/18/99
First Named Inventor	Awadhesh K. Mishra
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYEPHARMA

Sheet	12	of	12
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INFORMATION DISCLOSURE  
CITATION

ATTY. DOCKET NO.

SERIAL NO.

09/376,487

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MISHRA et al

FILING DATE

August 18, 1999

GROUP

1617

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(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
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OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

\*Examiner

Date Considered

10/01

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

Copies of initialed  
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Forms from parent  
application,  
USSN: 09/376,487

## INFORMATION DISCLOSURE CITATION

ATTY. DOCKET NO.

121-175

APPLICANT

MISHRA et al

FILING DATE

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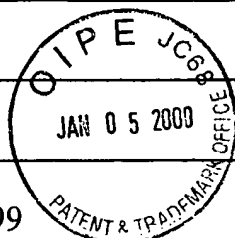
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09/376,487

**GROUP**

1617

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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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DISCLOSURE  
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PATENT & TRADEMARK OFFICE

09/376,487

**APPLICANT**

MISHRA et al

FILING DATE

**GROUP**

August 18, 1999

1617

## FILING DATE

## FOREIGN PATENT DOCUMENTS


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Substitute for form 1449A/B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	9/376,487
		Filing Date	August 18, 1999
		First Named Inventor	MISHRA
		Group Art Unit	1617
		Examiner Name	E. Webman
Sheet 1 of 2	Attorney Docket Number	402090	

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U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
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Examiner Signature		Date Considered	6/04
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 2 of 2

**Complete if Known**

Application Number 9/376,487  
Filing Date August 18, 1999  
First Named Inventor MISHRA  
Group Art Unit 1617  
Examiner Name E. Webman  
Attorney Docket Number 402090

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
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	65	PCT	WO 00/59472		Baxter International, Inc.	10/12/2000		
	66	PCT	WO 00/78301		Kuhnli Pharm. Co. Ltd.	12/28/2000		
	67	PCT	WO 01/30372		BASF Aktiengesellschaft	5/3/2001		X+
	68	PCT	WO 02/21517		Zeon Corp.	3/14/2002		X+
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	70	UK	2 250 197		Egis Gyogyszergyar	6/3/1992		
	71	UK	2 298 789		Zeneca Ltd.	9/18/1996		

Examiner Signature

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Date Considered

6/09

- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
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Substitute for form 1449A/B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	09/376,487
		Filing Date	August 18, 1999
		First Named Inventor	MISHRA
		Group Art Unit	1617
		Examiner Name	E. Webman
Sheet 1 of 3	Attorney Docket Number	402090/SKYE PHARMA	

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
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	2	"Diprivan 1% Injection," Physicians' Desk Reference, 1999, pp. 3411-18.		
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number 09/376,487  
Filing Date August 18, 1999  
First Named Inventor MISHRA  
Group Art Unit 1617  
Examiner Name E. Webman  
Attorney Docket Number 402090/SKYE PHARMA

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## **OTHER - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
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Examiner Signature

Date Considered

6/04

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	09/376,487
Filing Date	August 18, 1999
First Named Inventor	MISHRA
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYE PHARMA

Sheet 3 of 3

### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No*
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- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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of

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Application Number

09/376,487

Filing Date

August 18, 1999

First Named Inventor

MISHRA

Group Art Unit

1617

Examiner Name

E. Webman

Attorney Docket Number

402090/SKYE PHARMA

## **U.S. PATENT DOCUMENTS**

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Examiner Signature

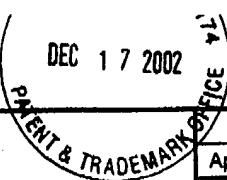
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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Application Number	09/376,487
Filing Date	August 18, 1999
First Named Inventor	MISHRA
Group Art Unit	1617
Examiner Name	E. Webman
Attorney Docket Number	402090/SKYE PHARMA

## U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	59	JP	10-251142		Michael	9/22/1998		X+
	60	JP	2000-119177		Torii Yakuhin KK	4/25/2000		X+
	61	JP	2002-179562		Towa Yakuhin KK	6/26/2002		X+
	62	PCT	WO 96/32135		Farmarc Nederland BV	10/17/1996		
	63	PCT	WO 02/074200		Cydex, Inc.	9/26/2002		
	64	UK	2 359 747		Maelor Pharmaceuticals Ltd.	9/5/2001		

Examiner Signature

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**INFORMATION DISCLOSURE  
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APPLICANT

MISHRA et al

FILING DATE

March 23, 2001

SERIAL NO.

to be assigned

GROUP

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**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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J	6,147,122	11/2000	Mirejovsky et al			
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J	6,177,477	1/2001	George et al			

**FOREIGN PATENT DOCUMENTS**

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
J WO 00/59471	10/2000	WIPO			
J WO 00/59472	10/2000	WIPO			
J WO 00/78301	12/2000	WIPO			
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J 0 770 387 A1	5/1997	Europe			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, etc.)**

Cox et al "Influence of different fat emulsion.." Pharmaceutical Research Vol. 15, No. 3, 3/1998, pp 442-448

\*Examiner

Date Considered

6/04

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.